Fishers Lane, Room 10–42, Rockville, MD 20857, (301) 443–1644.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.278, Drug Abuse National Research Service Awards for Research Training; 93.279, Drug Abuse Research Programs; 93.277, Drug Abuse Scientist Development Award for Clinicians, Scientist Development Awards, and Research Scientist Awards, National Institutes of Health, HHS)

Dated: November 2, 1998.

Anna Snouffer,

Acting Committee Management Officer, National Institutes of Health.

[FR Doc. 98–29985 Filed 11–6–98; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. Appendix 2), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5, U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Diabetes and Digestive and Kidney Diseases Special Emphasis Panel, ZDK1 GRB–8 (J3).

Date: December 2, 1998.

Time: 3 PM to Adjournment.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, Natcher Building, 45 Center Drive, Bethesda, MD 20982 (Telephone Conference Call).

Contact Person: Roberta J. Haber, Scientific Review Administrator, Review Branch, DEA, NIDDK, Natcher Building, Room 6AS–37, National Institutes of Health, Bethesda, MD 20892–6600, (301) 594–8898.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: November 2, 1998.

Anna Snouffer,

Acting Committee Management Officer, National Institutes of Health.

[FR Doc. 98–29986 Filed 11–6–98; 8:45 am]

BILLING CODE 4140–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Protection of Human Subjects: Categories of Research That May Be Reviewed by the Institutional Review Board (IRB) Through an Expedited Review Procedure

AGENCY: Office for Protection from Research Risks, National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: On November 10, 1997, the Office for Protection from Research Risks (OPRR), in consultation with the Food and Drug Administration (FDA), requested written comments relating to the proposed republication of the list that identifies certain research activities involving human subjects which may be reviewed by the Institutional Review Board (IRB) through the expedited review procedure authorized in 45 CFR 46.110. The comment period closed on March 10, 1998. OPRR and FDA received a combined total of 108 comments. After a review of the comments, OPRR and FDA are now simultaneously publishing identical revised lists of categories of research activities that may be reviewed by the IRB through the expedited review procedure.

EFFECTIVE DATES: The revised list is effective as of November 9, 1998.

FOR FURTHER INFORMATION CONTACT: Michele Russell-Einhorn, Director of Regulatory Affairs, Office for Protection from Research Risks (OPRR), National Institutes of Health, 6100 Executive Blvd., Suite 3B01, Rockville, MD 20892–7507 or telephone (301) 435–5649 (not a toll-free number).

SUPPLEMENTARY INFORMATION: The Federal Policy (Common Rule) for the Protection of Human Subjects was published in the **Federal Register** on June 18, 1991 (56 FR 28003) and is employed by 17 Executive Branch agencies. This Federal Policy requires adherence to certain requirements by Federal agencies [1] and institutions receiving support from those agencies for research activities involving human subjects. The Federal Policy has three cornerstones: review of any research involving human subjects by an IRB with limited exceptions, informed consent of all research subjects; and formal, written assurance of institutional compliance with the Policy. The Department of Health and Human Services' (HHS) codification of the Federal Policy can be found at 45 CFR Part 46, Subpart A.

Section _____.110 of the Federal Policy provides for expedited review procedures for certain categories of research involving no more than minimal risk, and for minor changes in approved research. This same section gives the Secretary, HHS, the authority to amend and republish the expedited review list as needed after consultation with the departments and agencies that are subject to the Federal Policy. The expedited review list that is referenced in the Federal Policy was originally published by the Secretary, HHS in 1981 (46 FR 8392, 46 FR 8980). It listed categories of research that could be reviewed by the IRB through an expedited review procedure. The FDA also references an expedited review list (21 CFR Part 56) for matters under FDA's jurisdiction. The HHS and FDA lists have differed slightly, in that item nine (9) on the 1981 HHS expedited review list regarding certain types of behavioral research is not included in the list referenced in 21 CFR 56.110.

The comments received in response to the OPRR and FDA proposed revision of the 1981 expedited review list that was published on November 10, 1997 (62 FR 60607) overwhelmingly supported the proposed revision of the list. Three commenters suggested that there should be no expedited review available at all. OPRR and FDA disagree with these three comments and believe that expedited review is an appropriate part of the IRB review process. In addition, a deletion of the expedited review process would require a regulatory change to Section 110 which is beyond the scope of this revision. Several commenters suggested changing the exemptions found at Section 101(b), a topic also outside the scope of this revision.

[1] The following agencies have adopted the Common Rule: Department of Agriculture, Department of Energy, National Aeronautics and Space Administration, Department of Commerce, Consumer Product Safety Commission, International Development Cooperation Agency-Agency for International Development, Department of Housing and Urban Development, Department of Justice, Department of Defense, Department of Health and Human Services, Department of Education, Department of Veterans Affairs, Environmental Protection Agency, National Science Foundation, Department of Transportation, Central Intelligence Agency, Social Security Administration.